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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,000	09/12/2003	Andrzej J. Chanduszko	106586.185US1	8600

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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,000	CHANDUSZKO, ANDRZEJ J.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/22/03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-38 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/28/04, 2/28/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: 1/21/05.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 24-26, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 24-26 refer to the anchor members configured at a desired angle from the plane of the device. Its unclear as to which plane the applicant is referring to, as a device can be defined in a number of planes.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-9, 12, 15-25 and 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Huebsch et al (US 5853422).

Regarding Claim 1, Huebsch teaches a device for closing a defect in septal tissue, comprising: a first side (14) adapted to be disposed on one side of the septal tissue and a second (16) side adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by at least one center joint (18), wherein

each of said first and second sides includes an anchor member (22), and wherein the anchor member of at least one of said first and second sides comprises a generally cylindrical member (12) split along the central portion of its length (20) to form an elongate oval (Fig. 3).

Regarding Claim 2, Huebsch teaches the device of Claim 1, wherein said at least one center joint (18) extends through the defect in the septal tissue (6) when said device is deployed at its intended delivery location.

Regarding Claim 3, Huebsch teaches the device of Claim 2, wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect (Column 4, proximate lines 39-46).

Regarding Claim 4, Huebsch teaches the device of Claim 1, wherein each of said first and second sides comprises a generally cylindrical member split along the central portion of its length to form an elongate oval (Fig. 3).

Regarding Claim 5, Huebsch teaches the device of Claim 4, wherein said first and second anchor members (14, 16) are three-dimensional.

Regarding Claim 6, Huebsch teaches the device of Claim 1, wherein said anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 7, Huebsch teaches the device of Claim 1, wherein said at least one center joint includes a stretchable elastomeric material (Column 3, proximate lines 49-63).

Regarding Claim 8, Huebsch teaches the device of Claim 7, wherein said at least one center joint includes a shape memory material (Column 3, proximate lines 64-67).

Regarding Claim 9, Huebsch teaches the device of Claim 8, wherein said at least one center joint includes nitinol (Column 3, proximate lines 64-67).

Regardng Claim 10, Huebsch teaches the device of Claim 9, wherein said at least one center joint comprises a nitinol film (Column 4, proximate lines 3-10).

Regarding Claim 12, Huebsch teaches the device of Claim 7, wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue (Column 7, proximate lines 44-56).

Regarding Claim 15, Huebsch teaches the device of Claim 1, wherein at least one of said first and second anchor members (14, 16) includes a tissue scaffold (22).

Regarding Claim 16, Huebsch teaches the device of Claim 15, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 17, Huebsch teaches the device of Claim 15, wherein each of said first and second anchor members (14, 16) includes a tissue scaffold.

Regarding Claim 18, Huebsch teaches the device of Claim 17, wherein said at least one center joint (18) is connected to said tissue scaffolds (22).

Regarding Claim 19, Huebsch teaches the device of Claim 1, wherein said device is retrievable. It is noted that any implanted medical prosthesis or implant may be retrieved by a number of means.

Regarding Claim 20, Huebsch teaches a device for closing a defect in septal tissue, comprising: a first side (14) adapted to be disposed on one side of the septal tissue and a second side (16) adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by a at least one center joint (18), wherein each of said first and second sides includes an anchor member (22) comprising a generally cylindrical member (12) split along the central portion of its length (20) to form an elongate oval, and wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect when said device is deployed at an intended delivery location (Column 4, proximate lines 39-46).

Regarding Claim 21, Huebsch teaches the device of Claim 20, wherein said anchor members include a material selected from the group consisting of metals, polymers, shape memory materials, bioresorbable materials, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 22, Huebsch teaches the device of Claim 21, wherein each of said elongate oval anchor members (22) is three-dimensional.

Regarding Claim 23, Huebsch teaches the device of Claim 22, wherein each of said elongate oval anchor members (22) is configured to minimize the septal profile of said device.

Regarding Claim 24, Huebsch teaches the device of Claim 23, wherein the arcs of said elongate oval anchor members are positioned at an angle θ from the plane of said device. It is noted that the anchors are inherently position at an angle θ from any plane of the device.

Regarding Claim 25, Huebsch teaches the device of claim 24, wherein each of said elongate oval anchor members (22) is concave in shape.

Regarding Claim 27, Huebsch teaches the device of Claim 20, wherein each of said first and second anchor members includes a tissue scaffold (22).

Regarding Claim 28, Huebsch teaches the device of Claim 27, wherein said tissue scaffold includes a material selected from the group consisting of polyester fabrics, Teflon-based materials, ePTFE, polyurethanes, metallic materials, polyvinyl alcohol (PVA), extracellular matrix (ECM), synthetic bioabsorbable polymeric scaffolds, collagen, drug-exuding materials, and combinations of the foregoing materials (Column 2, proximate lines 37-40).

Regarding Claim 29, Huebsch teaches the device of Claim 20, wherein said at least one center joint includes a stretchable elastomeric material (Column 3, proximate lines 49-63).

Regarding Claim 30, Huebsch teaches the device of Claim 29, wherein said at least one center joint includes a shape memory material (Column 3, proximate lines 64-67).

Regarding Claim 31, Huebsch teaches the device of Claim 30, wherein said at least one center joint includes nitinol (Column 3, proximate lines 64-67).

Regarding Claim 32, Huebsch teaches the device of Claim 29, wherein said at least one center joint includes a material that promotes closure of the defect in the septal tissue (Column 7, proximate lines 44-56).

5. Claims 20, 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Sideris.

Regarding Claim 20, Sideris teaches a device for closing a defect in septal tissue, comprising: a first side (34) adapted to be disposed on one side of the septal tissue and a second side (38) adapted to be disposed on the opposite side of the septal tissue, said first and second sides connected by a at least one center joint (42), wherein each of said first and second sides includes an anchor member (34, 38) comprising a generally cylindrical member split along the central portion of its length to form an elongate oval (applicant is directed to figure 3 and column 5 proximate lines 25-30 Sideris' anchor 34 is referred to as a disc with a rounded shape, and any object has some height associated with it which therefore makes the disk 34 cylindrical with an open center portion or slit) and wherein said first and second sides cooperate to provide a compressive force to the septal tissue surrounding the defect when said device is deployed at an intended delivery location (Column 3, proximate lines 30-43).

Regarding Claim 34, Sideris teaches the device of Claim 20, further comprising a retrieval mechanism (18, 44) for retrieving said device from its intended delivery location.

Regarding Claim 35, Sideris teaches the device of Claim 34, wherein said retrieval mechanism reduces the profile of said device such that said device may drawn into a catheter (fig. 4).

Regarding Claim 36, Sideris teaches the device of Claim 35, wherein said retrieval mechanism reduces the distance between said first and second anchor members and aligns said first and second anchor members in a longitudinal orientation (fig. 4).

Regarding Claim 37, Sideris teaches the device of Claim 35, wherein said retrieval mechanism comprises a string extending from one end of said first anchor member to and through said second anchor member (44), and a ball constrained on said string within said second anchor member (connection of string 44 to skeleton wire 40). It is noted that according to Merriam Webster, the definition of ball is as follows: a round or roundish body or mass. Further, the knot or tie at the connection of the string 44 to skeleton wire 40 is roundish.

Regarding Claim 38, Sideris teaches the device of Claim 37, wherein said string (44) is flexible. It is noted that string (44) is comprised of nylon thread which is inherently flexible.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 13 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Hannam (US 5649959). Huebsch teaches all aspects of preceding dependent claims as previously described, but Huebsch does not disclose using glue, thrombogenic materials, or growth factors to accelerate tissue ingrowth, but Hannam discloses a similar anchor member 30 (see Fig. 12) and teaches injecting such materials (fibrin glue, cyanoacrylate, etc.) (column 8 lines 32-47) in conjunction with plug 30 in order to form a blood clot more quickly and allow the tissue to heal more quickly. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to apply fibrin glue to Huebsch's closure device in order to more rapidly form a blood clot (column 8 line 55),
as taught by Hannam.

8. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch in view of Kanesaka et al (US 5776183). Huebsch teaches all aspects of preceding dependent claims 1 and 7, but fails to disclose wherein said at least one center joint is porous or comprises holes. Kanesaka teaches a medical prosthesis

comprising pores to absorb or retain a drug for slow release. It would have been obvious to on one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch with a porous material as taught by Kanesaka in order to slowly release a drug into the tissue.

9. Claim26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch as a matter of design choice. Huebsch teaches all aspects of preceding claims 20-24 as previously described, but fails to disclose wherein said angle θ is greater than 0 degrees and less than about 45 degrees. It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure angle θ to be greater than 0 degrees and less than about 45 degrees since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum workable ranges involves only ordinary skill in the art. In re Aller, 105 USPQ 233.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP
1/3/06

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER